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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/538,829	03/30/2000	Pankaj Modi	358594-00010-2	8342

7590 12/20/2004

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EXAMINER
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SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/20/2004

21

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/538,829

**Applicant(s)**

MODI, PANKAJ

**Examiner**

Humera N. Sheikh

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-34,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-34,36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### **Status of the Application**

In view of the Board of Patent Appeals and Interferences Decision, prosecution is being continued on the instant application.

Claims 26-34, 36 and 37 are pending. Claims 26-34, 36 and 37 are rejected.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 26, 27 and 29 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3 and 4 of prior U.S. Patent No. 6,432,383. This is a double patenting rejection.

The instant application ('829) is drawn to a method for administering insulin to the buccal mucosa comprising spraying an effective amount of said insulin to the buccal mucosa using a metered dose inhaler, while resisting substantial inhalation of said insulin.

Claim 1 of U.S. Patent No. 6,432,383 is drawn to a method for administering insulin to the buccal mucosa comprising spraying an effective amount of said insulin to the buccal mucosa using a metered dose inhaler.

The limitation 'resisting substantial inhalation of said insulin' recited in claim 26 of instant '829 Application is inherent in the formulation of U.S. Pat. '383 since the same drug (insulin) is used, in the same amount (effective amount) using the same method of administration (spraying to buccal mucosa using a metered dose inhaler).

Claim 27 of instant application '829 recites that the 'insulin is in a mixed micelle formulation.' Claim 3 of U.S. Pat. '383 also claims that the 'insulin is in a mixed micelle formulation.

Likewise, Claim 29 of application '829 recites that 'micelles are 1 to 10 nm in size.' Claim 4 of U.S. Pat. '383 also claims that 'micelles are 1 to 10 nm in size.' Thus, the inventions of claims 26, 27 and 29 of instant application '829 and that of claims 1, 3 and 4 of U.S. Patent '383 are the same.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-34, 36 and 37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,432,383. Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed.

Claim 26 of instant application ('829) is drawn to a method for administering insulin to the buccal mucosa comprising spraying an effective amount of said insulin to the buccal mucosa using a metered dose inhaler, while resisting substantial inhalation of said insulin.

Claim 1 of U.S. Patent No. 6,432,383 is drawn to a method for administering insulin to the buccal mucosa comprising spraying an effective amount of said insulin to the buccal mucosa using a metered dose inhaler.

The difference between claim 26 of instant application '829 and claim 1 of Patent '383 is the limitation 'resisting substantial inhalation of said insulin' included in claim 26 of '829. However, such a limitation would have been obvious in the formulation of U.S. Pat. '383 since the same drug (insulin) is used, in the same amount (effective amount) using the same method of administration (spraying to buccal mucosa using a metered dose inhaler).

Claim 28 of instant application '829 is drawn to a method for administering insulin to the buccal mucosa, wherein said formulation comprises: alkali metal ( $C_8$ - $C_{22}$ ) alkyl sulfate, a pharmaceutically acceptable edetate, at least one alkali metal salicylate, at least one micelle forming compound (lecithin, hyaluronic acid....triolein and mixtures thereof), wherein each of said sulfate, edetate and salicylate is present in a concentration of from 1 to 10 wt./wt.%....and the total concentration of sulfate, edetate, salicylate and micelle forming compounds is less than 50 wt./wt.% of the formulation.

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Claim 5 of U.S. Pat. '383 is also drawn to a method for administering insulin to the buccal mucosa, wherein said formulation comprises: insulin, alkali metal lauryl sulfate, a pharmaceutically acceptable edetate, at least one alkali metal salicylate, at least one micelle forming compound (lecithin, hyaluronic acid....triolein and mixtures thereof), wherein each of said sulfate, edetate and salicylate is present in a concentration of from 1 to 10 wt./wt.%....and the total concentration of sulfate, edetate, salicylate and micelle forming compounds is less than 50 wt./wt.% of the formulation. The only difference between claim 28 of instant application '829 and claim 5 of Pat. '383 is that '829 application recites an 'alkali metal C<sub>8</sub>-C<sub>22</sub> alkyl sulfate, whereas claim 5 of Pat. '383 recites an 'alkali metal lauryl sulfate'. Claim 28 is rejected under obvious-type double patenting over claim 5 of Pat. '383 since the species recited in claim 28 anticipates the generic claimed in Pat. '383.

Similarly, claims 30-34, 36 and 37 of instant application '829 are rejected over claims 2 and 5-11 of Patent '383 since the species recited in '829 anticipates the generic of Patent '383. The reference is deficient only in the sense that it does not teach Applicant's specific formulations being claimed. However, the reference does teach Applicant's selective ingredients and does teach the selective ingredients and amounts to be obvious.

In view of claim 3 of the '383 Patent, which permits mixed micelle formulations, it would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the claimed ingredients, such as sodium lauryl sulfate, alkali metal edetate, sodium salicylate, lecithin and water, since each of these are disclosed in the reference patent as being suitable for administering insulin by the use of a metered dose inhaler.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh *H.N.S.*

Patent Examiner

Art Unit 1615

December 17, 2004

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